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74

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,939	09/22/2003	Micheal E. Nicholson	2228-1-3	3323

7590 04/18/2005

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EXAMINER

REICHLER, KARIN M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5P

Office Action Summary	Application No. 10/668,939	Applicant(s) NICHOLSON, MICHEAL E.	
	Examiner Karin M. Reichle	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9-22-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the invention of Group I filed 3-35-05 is noted as is the cancellation of claims 14-15. As claim 14 -15 were cancelled, the restriction requirement set forth in the 2-24-05 Office Action is withdrawn at this time. It is further noted that the 3-25-05 response is not in compliance with 37 CFR 1.121 effective 7-30-03 because it does not include a full listing of all the claims as well the appropriate parentheticals, e.g. --(original)-- and --(cancelled)--. Any further response in this application must include such full listing with the then appropriate parentheticals.

Oath/Declaration

2. The initialed correction to the name of the inventor in the oath is noted.

Specification

Drawings

3. The drawings are objected to because Figure 1 should be labeled "PRIOR ART". Also Figure 1 and the description thereof in paragraph 10 are not consistent, i.e. Figure 1 is a cross section. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended

Art Unit: 3761

drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Description

4. The disclosure is objected to because of the following informalities: The description of Figure 1 in paragraph 10 is inconsistent with Figure 1, i.e. Figure 1 is prior art and in cross section. Also in paragraph 1, “priority from” should be -- the benefit of--. On page 6, line 4, “surged” should be --serged--.

Appropriate correction is required.

5. The use of the trademarks in paragraphs 15, 23 and 27 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Trademarks should be shown in all capital letters or with the trademark symbol but not both.

Claim Objections

6. Claims 1-13 are objected to because of the following informalities: in claim 1, “colostomy” should be --ostomy-- and in claim 9, line 1 “in” should be deleted. Appropriate correction is required.

Claim Language Interpretation

7. In claim 1, the terminology “at least one low coefficient of friction surface” is considered relative absent claiming of specific dimensions thereof. See, for example, claim 9. Furthermore, it is noted that in paragraph 21 a low coefficient of friction surface includes surfaces of a material having a smooth, silky or satiny surface. Also, in claim 1 the terminology “breathable” is also considered relative absent claiming of specific dimensions thereof. Furthermore, it is noted that in paragraph 22 a breathable material includes fabric materials having a weave and perforated materials. In claims 3-4 and 13 the configurations of certain structures are defined in terms of function, capability or properties. See rejections *infra*.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3761

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Honig '054.

Claims 1, 8, 10-12: see Figures 1 and 3-4, col. 1, lines 47-49, col. 2, lines 14-16, 44-47 and 65 et seq, col. 3, lines 1-5, col. 4, lines 10-14, 18-19, 21-24, 32-34 and 55-56, col. 5, lines 15-21 and claims, the Claim Language Interpretation section supra, the dictionary definition of “soft” which is “smooth or fine to the touch”, “easily molded, cut, or worked”, “yielding readily to pressure or weight”, the dictionary definition of “fabric” which is “a cloth produced especially by knitting, weaving or felting fibers”, the dictionary definition of “flexible” which is “capable of being bent or flexed, pliable”, the dictionary definition of “resilient” which is “the property of material that enables it to resume its original shape or position after being bent, stretched or compressed, elasticity”, i.e. the first and second sheets are 42 and 40 of soft, i.e. smooth, easily molded, yielding, cotton fabric, i.e. woven, which are dimensioned to substantially cover respective first and second portions of an ostomy appliance, the second sheet including a resilient member which defines an aperture, opening or perforation which can be expanded to allow the appliance to pass therethrough. It is the Examiner’s first position that the Honig reference teaches first and second sheets of flexible material because it teaches a soft fabric, i.e. moldable, yieldable, that the first sheet has at least one low coefficient of friction surface either because it teaches a soft, i.e. smooth, surface or/and the terminology “low coefficient of friction” is relative, that the second sheet is elastic and breathable and allows passing without distortion because it is woven fabric and/or it includes resilient opening or perforation 48. In any case, the Examiner’s second position, the Honig device teaches first and second soft fabric, i.e. smooth, yielding,

Art Unit: 3761

woven, sheets dimensioned to substantially cover the appliance and the second sheet includes an expandable, i.e. resilient, opening for passing of the appliance therethrough. Therefore, even if the reference does not explicitly teach the properties of flexibility, low friction, elasticity, breathability and no substantial distortion, there is sufficient factual basis for one to conclude that the properties, functions and capabilities are also inherent in the structure of the Honig device since it also teaches the same structure claimed and/or disclosed as providing such properties, functions and capabilities in the instant application, see MPEP 2112.01.

Claim 2: see, e.g., claim 5 of Honig.

Claims 3-4 and 13: Claims 3-4 recite the sheets include a configuration to lay proximate to the respective appliance portions without substantial wrinkling and claim 13 recites the opening having a configuration that when expanded allows the appliance to pass therethrough without substantial distortion. In light of the discussion of claim 1 supra and Figure 4 which shows the sheets laying proximate without wrinkling it is the Examiner's first position that the Honig device teaches the claimed structure and function, capabilities and properties. In any case, the Examiner's second position, the Honig device teaches first and second soft fabric, i.e. smooth, yielding, woven, sheets dimensioned and configured to substantially cover and lie proximate the appliance and the second sheet includes an expandable, i.e. resilient, opening for passing of the appliance therethrough. Therefore, even if the reference does not explicitly teach the properties, functions and capabilities of claims 3-4 and 13 there is sufficient factual basis for one to conclude that the properties, functions and capabilities are also inherent in the structure of the Honig device since it also teaches the same structure claimed and/or disclosed as providing such properties, functions and capabilities in the instant application, see MPEP 2112.01.

Claims 5-6: see Figures of Honig.

Claim 7. This claim recites the periphery of the expandable opening includes stretchable stitching. "Stitch" as defined by the dictionary is "a single loop of yarn around an implement such as knitting needle", "the link, loop or knot made in this way". Honig teaches an expandable opening including a ribbed aperture constructed of a resilient member. See the definition of "resilient" supra, i.e. stretchable, and the dictionary defines "ribbed" as "a raised ridged or wale in knitted material or cloth" and "knitted" as "to make or fashion by intertwining yarn or thread in a series of connected loops either on a machine or by hand". Therefore, Honig teaches an expandable opening including stretchable stitching.

Claim Rejections - 35 USC § 103 .

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honig.

Claim 9 recites the range of coefficients of friction which are considered to provide low friction surfaces, i.e. smooth surfaces. While Honig does not teach such specific range of smoothness it does teach the desirability of using a soft, i.e. smooth, surfaced fabric to form the first and second sheets. Furthermore, where the general conditions of a claim are disclosed in the prior art, i.e. in the present case the smoothness of the fabric, it is not inventive to discover the

Art Unit: 3761

optimum or workable ranges thereof by routine experimentation, see *In re Aller et al*, 105 USPQ 233.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The other cited prior art also teaches various covers or low coefficient of friction materials.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

K.M. Reichle
Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
April 6, 2005